

### **REMARKS**

In response to the Non-Final Office Action mailed on January 20, 2010, Applicant submits the following amendments and remarks in an effort to address the rejections raised in the Office Action and to facilitate prosecution.

#### **Election of Species**

The Examiner required election of a specific combination of biologically-active factors to which examination of claims 27-35 would be restricted. Applicant elected TNF- $\alpha$  and IL-12 in the response filed on January 3, 2007. The Examiner noted that examination of claims 27-35 was restricted to the elected combination in the Non-Final Office Action mailed October 17, 2007. The art cited below under 35 U.S.C. § 102(b) in the present Office Action is clearly not restricted to the elected combination above as neither of the cited references teaches a composition comprising TNF- $\alpha$  and IL-12. In addition, under the double patenting rejection below, the Examiner states the claims of the cited patent provide anticipatory species encompassed within the broad genus style claims of claims 27-35. See item 5 on page 6 of Office Action. Therefore, it is the Applicant's understanding that the election of species requirement has been withdrawn by the Examiner as improper as no serious burden for searching the broader genus appears to exist.

#### **Amendments to the Claims**

Claims 27-31 and 35-48 are pending in the present application, with Claims 27, 29 and 30 being independent. Applicant has herein amended Claims 27-31 and 35. Applicant also has added new Claims 36-48 to provide an additional scope of protection commensurate with the original disclosure. Additionally, Applicant has canceled Claims 32-34 herein without prejudice to, or disclaimer of, the subject matter recited therein. No new matter has been added.

Unless explicitly stated otherwise, none of the amendments to the claims were made for reasons substantially related to the statutory requirements for patentability. Furthermore, unless stated otherwise, the amendments to the claims were made simply to make express what had

been implicit in the claims as originally worded and therefore are not narrowing amendments that would create any type of prosecution history estoppel.

*Claim Objections*

In the Non-Final Office Action mailed January 20, 2010, the Examiner objected to Claims 28, 30, 31, and 34 because of the following informalities. Specifically the Examiner indicated that the terms “sense”, “antisense”, “cancer”, and “cell specific antigens” can be amended to better clarify the nature of the invention. Applicant submits the amendments to the claims address the above informalities and requests that the objections be withdrawn.

*Claim Rejections Under 35 U.S.C. § 102*

In the Office Action, the Examiner rejected Claims 27 and 29 under 35 U.S.C. § 102(b) as allegedly being unpatentable over U.S. Patent No. 4,740,589 to Moreno (hereinafter Moreno). Applicant respectfully submits the amendments to the claims, in conjunction with the remarks below, overcome this rejection.

The Examiner asserts that Moreno teaches a method of vaccinating a subject by administering a composition comprising a metal constituent (e.g. aluminum or ruthenium) and a bacterial capsular polysaccharide that contains sialic acid and a third constituent of a bacterial outer-membrane protein. The Examiner asserts that the antigens of the composition function as target molecules in that they direct to the composition to preferential uptake by antigen presenting cells.

The Examiner further rejected Claims 27, 29 and 32 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 3,269,912 to Grafe (hereinafter Grafe). Applicant respectfully submits the amendments to the claims, in conjunction with the remarks below, overcome this rejection.

The Examiner asserts that Grafe teaches a method wherein a complex comprising an aluminum oxide colloiddally dispersed in an aqueous medium and carrying at least one antigen is used as a vaccine. The Examiner further asserts that the antigens function as a target molecule in

that they direct the preferential uptake of the antigens by antigen presenting cells. Applicants further note that the antigens for use in the composition of Grafe are limited to "...being a member of the group consisting of the viruses, the bacteria, the endotoxins, the ectotoxins and the corresponding toxoids" (Grafe – Column 7, lines 45-55).

#### Independent Claims 27, 29 and 30

Applicant submits that both Moreno and Grafe fail to teach at least the following features; a composition comprising one or more cytokines and a target molecule admixed with or bound to a colloidal metal, as presently recited in independent claim 27; a composition comprising one or more chemotherapeutics and a target molecule as presently recited in independent claim 29; and a composition comprising a target molecule and one or more of the biologically active factors presently recited in claim 30.

Thus, Applicant submits that independent Claims 27, 29 and 30 are patentable over Moreno and Grafe. Additionally, the remaining claims depend from one of the independent claims either directly or indirectly and are submitted to be patentable for similar reasons. For at least the foregoing reasons, Applicant submits the rejections under 35 U.S.C. § 102(b) have been overcome, and respectfully requests that they be withdrawn.

#### Claim Rejections – Double Patenting

In the Non-Final Office Action mailed January 20, 2010, the Examiner rejected claims 27-35 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-21 of U.S. Patent No. 6,274,552. The Examiner asserted that the instant claims are broader in scope than the claims of the '552 patent and thus, the instant claims are anticipated by the narrower claims of the broader (genus-type) claims. The claims of the '552 patent are directed to the use of a composition comprising TNF alpha or lymphotoxin and a target molecule. The '552 patent is not directed to the use of a composition comprising one or more cytokines and a target molecule, one or more chemotherapeutics and a target molecule, or a target molecule and one or more the biologically active factors presently recited in claim 30. In addition, TNF alpha

and lymphotoxin are not anticipatory species of cytokines, chemotherapeutics, or the biologically active factors presently recite in claim 30. Accordingly, claims 8-21 of the '552 patent do not anticipate the presently claimed invention. For at least the foregoing reasons, Applicant respectfully request that the double patenting rejection be withdrawn.

No Waiver

All of Applicant's arguments and amendments are without prejudice or disclaimer. Applicant has not addressed each specific rejection of the independent and dependent claims because Applicant submits that the independent claims are allowable over the documents of record, as discussed above. Applicant has not acquiesced to any such rejection and reserves the right to address the patentability of any additional claim features in the future.

**CONCLUSION**

Applicant submits the foregoing as a full and complete response to the Official Action dated January 20, 2010. Applicant submits that this Amendment and Response places the application in condition for allowance and respectfully request such action. If any issues exist that can be resolved with an Examiner's Amendment or a telephone conference, please contact Applicant's undersigned attorney at 404.665.3099

Respectfully submitted,

**/F. Brent Nix/**

F. Brent Nix  
Reg. No. 59,004

Johnson & Associates  
317A E. Liberty Street  
Savannah, Georgia 31401  
Tel: 912.257.4864  
Attorney Docket No: CYT-0027